JAN 1 2 2001

K003783

510(K) SUMMARY
(as required by 807.92(c))

Submitter of 510(k):

Medical Depot, Inc.
1010 Northern Blvd., Suite 314
Great Neck, NY 10021

Phone: 516-465-4338
Fax: 516-465-4342

Contact Person: Doug Francis

Date of Summary: November 1, 2000

Trade Name: Medical Depot – Wheelchairs Models: Sentra, Astaire and Viper

Classification Name: Mechanical Wheelchair

Predicate Device: Medline Excel Wheelchairs K990463

Intended Use:

The Medical Depot Wheelchair is intended to be used to provide mobility to persons restricted to a sitting position.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2001

Medical Depot, Inc.
Mr. Art Ward
Regulatory Consultant
c/o Regulatory & Marketing Services, Inc.
3234 Ella Lane
New Port Richey, Florida 34655

Re: K003783
Trade Name: Medical Depot-Wheelchairs, Model Sentra, Astaire And Viper
Regulatory Class: I
Porduct Code: IOR
Dated: November 1, 2000
Received: November 7, 2000

Dear Mr. Ward:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Medical Depot Wheelchair – Sentra, Astaire and Viper

Indications For Use:

The Medical Depot Wheelchair is intended to be used to provide mobility to persons restricted to a sitting position.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K003783

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)